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A LOUVE AND A	Attorney Docket No.		BSC-035CN o							
UTILITY PATENT APPLICATION	First Named Inventor		Gellman et al.							
TRANSMITTAL (Only for new nonprovisional applications under 37 CFR 1.53(b))	Title		BONE ANCHORS FOR BONE ANCHOR IMPLANTATION DEVICE							
A DDI ICATION EL EMENTO		ADDRESS	TO: Box Patent A	pplication						
APPLICATION ELEMENTS			Assistant Commissioner for Patents Washington, D.C. 20231							
1. Fee Transmittal Form		A	ACCOMPANYING APPLICATION PARTS							
Specification and Drawings [Total Pages 15] - Specification - (10 pages) - Claims - (2 pages)		7. 37 CFR 3.73(b) Statement (when there is an assignee) Power of Attorney								
- Abstract - (1 page) - Sheets of Drawings - (2 sheets)		8. English Translation Document (if applicable)								
Formal Informal				9. Information Disclosure Statement (IDS)/PTO-1449 Copies of IDS Citations						
3. Oath or Declaration [Total Pages]		10. P1	eliminary Amendme	nt						
 a. Newly executed (original) b. Copy from a prior application (37 CFI 1.63(d)) (for continuation/divisional with Box 17 continuation (37 CFI) 	☐ Drawings [Total Sheets] ☐ Letter to Official Draftsperson Including ☐ Drawings [Total Pages]									
[Note Box 4 below]	ompresedy	11. Return Receipt Postcard								
Incorporation by Reference (usable if Box 3b is checked) The entire Disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 3b, is considered as being part of the		12. Small Entity Statement(s) Statements filed in prior application, (Status still proper and desired) 13. Certified Copy of Priority Document(s)								
disclosure of the accompanying application are hereby incorporated by reference therein.	Id Is			 						
5. Microfiche Computer Program (Appendix)		Si	eletion of Inventor(s gned statement attac e prior application.) hed deleting inventor(s) n	amed in					
6. Nucleotide and/or Amino Acid Sequence Sub	mission		atent Application Da	ta Entry Form						
Computer Readable Copy Paper Copy (identical to computer cop Statement verifying identify of above of		16. 🗌 O	ther:							
17. If a CONTINUING APPLICATION, check appropriate box and supply the requisite information: Continuation Divisionar Continuation-in-part (CIP) of prior application Serial No. 09/238.663. Priority to the above application(s) is claimed under 35 U.S.C. 120. Prior application information: Examiner: Ho, U. Group/Art Unit: 3731.										
18. Priority - 35 U.S.C. 119 Priority of application Serial No. filed on in the U.S. Patent Office is claimed under 35 U.S.C. 119. The certified copy has been filed in prior U.S. application Serial No/ on										
The certified copy will follow. CORRESPONDENCE ADDRESS			SIGNATURE BLOCK							
Direct all correspondence to: Patent Administrator Testa, Hurwitz & Thit High Street Tower 125 High Street Boston, MA 02110 Tel. No.: (617) 248-70 Fax No.: (617) 248-71	000	Reg. No Tel. No.	fay 26, 2000 . 42,545 : (617) 248-7216 : (617) 248-7100	Respectfully submitted John V. Forcier Attorney for the Application of the Application o	cants					

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Correspondence Information

Correspondence Customer Number :: 021323

Application Information

Title Line One :: Bone Anchor for Bone Anchor Implantation Device

Title Line Two ::

Total Drawing Sheets :: 2
Formal Drawings :: Y
Application Type :: Utility
Docket Number :: BSC-035CN

Licensed - U S Government Agency ::

Contract Number :: Grant Number ::

Secrecy Order in Parent Application ::

Representative Information

Representative Customer Number :: 021323

Continuity Information

This application is a :: >Application One :: Filing Date ::

Claims Benefit

60/072,639

January 27, 1998

This application is a ::

>>Application Two :: Filing Date ::

Continuation of 09/238,663

January 26, 1999

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PATENT APPLICATION Atty. Docket No.: BSC-035

Bone Anchors For Bone Anchor Implantation Device

Cross Reference to Related Applications

This application claims priority to and the benefit of U.S. Provisional Patent Application Serial No. 60/072,639 filed January 27, 1998. The entirety of this priority document is hereby incorporated by reference.

Technical Field

This invention relates to various bone anchor designs for use in a bone anchor implantation device.

Background Information

Urinary incontinence, the inability to control urination from the bladder, is a widespread problem that affects people of all ages. Urinary incontinence is more prevalent in women than in men. Urinary incontinence in women is typically causes by intrinsic spincter deficiency (ISD), a condition in which the valve of the urethral spincter do not properly coapt, or by hypermobillity, a condition in which the muscles around the bladder relax, causing the bladder neck and proximal urethra to rotate and descend in response to increases in intraabdominal pressure. Hypermobilty may be the result of pregnancy or other conditions which weaken the muscles. Urinary incontinence in men can be caused by post radical prostatectomy, which destroys the valves of the urethral spincter. Urinary incontinence can also be caused by birth defects, disease injury, aging and urinary tract infection.

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Numerous approaches for treating urinary incontinence are available. One treatment is a surgical operation to return the bladder and proximal urethra to their normal anatomical positions by elevating them in order to reduce intraabdominal pressure. There are also noninvasive procedures for stabilizing and/or slightly compressing the urethra so as to prevent the leakage of urine. For example, a stabilizing or compressive force may be applied by sutures passing through the soft tissue surrounding the urethra or, alternatively, may be applied by means of a sling suspended by sutures. In some procedures bone anchors are inserted in the pubic bone or symphysis pubis in order to anchor the suture to the bone. Often an anchor receiving hole is drilled into the bone prior to inserting the anchor. Other bone anchor devices incorporate a drill for predrilling an opening in the bone thus eliminate the need for a predrilling step.

Summary of the Invention

The present invention relates to a bone anchor implantation device for driving a bone anchor into the bone by the application of a retrograde force. More particularly, the present invention relates to improved bone anchors. Bone anchor configurations according to the invention reduce the amount of force required to secure the bone anchor into a bone anchor implantation site.

Bone anchors are often attached to bones in order to provide support for a "sling" useful in improving or maintaining a patient's urinary incontinence. In one procedure, a suture carrying anchor is driven through the vaginal wall and into the posterior portion of the pubic bone or symphysis pubic, and the suture(s) attached to the bone anchor(s) extend through the vaginal wall and may be attached to the endopelvic fascia, the vaginal wall, a sling, or other material to stabilize and/or slightly compress the urethra thereby improving the patient's urinary incontinence. The present invention effectively addresses concerns in affixing an anchor to bone or tissue.

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The present invention is directed to a bone anchor which implants into the bone and supports a suture. The bone anchor, which releasable engages to a bone anchor implantation device, comprises a generally cone-shaped head with at least two, preferably three, cutting edges which come together to form a pointed tip at the end of the anchor that first contacts the target site. The cutting edges on the generally cone-shaped head can be defined by flat planar surfaces or outward curved surfaces. These bone anchor configurations reduce the amount of force and pressure that a user (i.e. a surgeon) of a bone anchor implantation device must apply to implant the bone anchor into the bone.

In general, one aspect of the present invention involves a bone anchor for use with a bone anchor implantation device. The bone anchor comprises a generally cone-shaped head which has a wide end, a narrow end, and at least two cutting edges. At the narrow end of the generally cone-shaped head, the cutting edges come together to form a pointed tip. The wide end of the head can releasably engage to a bone anchor implantation device.

Embodiments of this aspect of the invention can include the following features. The cutting edges can be defined by flat surfaces or curved surfaces. The cutting edges can be formed in various ways such as by cutting or scalloping the surface of the bone anchor. Also, the cutting edges can be sharp edges. In a preferred embodiment, there are three cutting edges which come together to form the pointed tip at the narrow end.

In an alternative embodiment, the bone anchor further comprises a collar member for retaining the bone anchor in place. The collar member is coupled to the wide end of the generally cone-shaped head. The bone anchor can also comprise a shaft with an eyelet for receiving a suture. The shaft is coupled to the wide end of the generally cone-shaped head.

In general, another aspect of the invention relates to a bone anchor implantation device comprising a handle having a proximal and a distal end, a hooked-shaped shaft, a bone anchor mount attached at the distal end of the shaft

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and a bone anchor releasably engaged to the bone anchor mount. The bone anchor comprises a generally cone-shaped head with a wide end which engages to the bone anchor mount, a narrow end, and at least two cutting edges which come together to form a pointed tip at the narrow end. The bone anchor can have various configurations, such as cutting edges defined by flat or curved surfaces. The bone anchor is inserted into a bone by applying a retrograde force to the bone anchor implantation device.

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The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description and from the claims.

Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

Figure 1 is a side view of a bone anchor according to the invention with curved surfaces defining the cutting edges.

Figure 2 is another view of the bone anchor according to the invention of Figure 1.

Figure 3 is a side view of a bone anchor according to the invention with flat cutting edges.

Figure 4 is another view of the bone anchor of Figure 3.

Figure 5 is a side view of a bone anchor according to the invention having a generally cone-shaped head with cutting edges and a collar member.

Figure 6 is a side view of a bone anchor implantation device with a hook-shaped shaft.

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Description

A bone anchor according to the invention has a generally cone-shaped head with a wide end, a narrow end, and at least two cutting edges which come together to form a pointed tip at the narrow end of the head. The bone anchor is utilized in a bone anchor implantation device. The various bone anchor configurations of the present invention reduce the amount of force required to drive the bone anchor into the bone.

Representative bone anchors are illustrated in Figures 1-4. The bone anchors 22 comprise a generally cone-shaped head 14 which is able to pierce and securely engage the bone, and the bone anchors 22 generally require less force than conventional bone anchors to drive them into bone. The generally cone-shaped head 14 has a wide end 18, a narrow end 19, and at least two cutting edges 26 which come together to form a pointed tip 24 at the narrow end 19. The generally cone-shaped head 14 is coupled to a shaft portion 16. The shaft portion 16 of the bone anchor 22, which is generally cylindrical in shape, can be releasably engaged to a bone anchor implantation device 28. Only a portion of the device 28 is shown in Figures 1-5.

The generally cone-shaped head 14 of the bone anchor 22 is located at an end of the shaft portion 16 opposite the end which attaches to the bone anchor implantation device 28. The apex of the generally cone-shaped head is a point 24 which is suitable for piercing and being driven into bone. The diameter of the generally cone-shaped head 14 increases in the longitudinal direction from the point 24 towards the shaft portion 16.

As shown if Figures 1-4, the generally cone-shaped head 14 of the bone anchor 22 has at least two, preferably three or more, cutting edges 26. The cutting edges 26 can extend the length of the generally cone-shaped head 14, and they come together at the point 24. Preferably, the cutting edges are sharp. The cutting edges reduce the amount of force that is necessary to implant the bone anchor into the bone.

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In some embodiments, such as that shown in Figures 1 and 2, the cutting edges 26 on the bone anchor 22 are defined by curved or scalloped surfaces 25 formed in the anchor 22. These surfaces 25 are cut into the generally cone-shaped head 14. These arcuate surfaces 25 form and define the cutting edges 26 and they generally extend from the wide end 18 of the generally cone-shaped head 14 to the narrow end 19 of the generally cone-shaped head 14.

In other embodiments such as that shown in Figures 3 and 4, the cutting edges 16 on the bone anchor 22 are defined by flat surfaces 23 formed in the anchor 22. The flat surfaces 23 are cut into the generally cone-shaped head 14. The flat surfaces 23 extend generally from the wide end 18 to the narrow end 19 of the generally cone-shaped head 14.

Preferably, the generally cone-shaped head 14 is formed integrally with the shaft portion 16 of the bone anchor 22. Alternatively, the generally cone-shaped head 14 and the shaft portion 16 may initially be formed separately and then subsequently attached to one another.

Any known materials suitable for orthopedic anchor devices may be employed to construct the bone anchor 22 of the present invention. Preferably, the bone anchor 22 is formed from a metallic material possessing sufficient strength to penetrate the bone. Such materials include titanium 316 LVM stainless steel, CoCrMo alloy, Nitinol alloy, or other suitable materials. In a preferred embodiment, the bone anchor is formed from titanium.

Another embodiment of a bone anchor according to the invention is illustrated in Figure 5. The bone anchor 22 of Figure 5 comprises a generally coneshaped head 14 which is able to pierce and securely engage bone. The generally cone-shaped head 14 is coupled to a shaft portion 16 with an oval eyelet 18 therethrough for receiving and holding one or more suture strands. To retain the generally cone-shaped head 14 within the bone, the bone anchor 22 further comprises a collar member 20. The collar member 20 is used for retaining the

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bone anchor 22 in place, once it has been driven into the bone, by lodging within the bone in a manner to resist removal of the bone anchor 22.

The shaft portion 16 of the bone anchor 22 is generally cylindrical in shape and has the eyelet 18, or bore, formed radially therethrough proximate one of its ends. The eyelet 18 may be oval, round, or other suitable shape and is of a sufficient size to permit one or more suture strands to pass therethrough. The circumference of each outer end of the eyelet 18 is chamfered or grounded to provide a bevel portion 22. It should be appreciated that the bevel portion 22 provides a generally smooth surface for contacting suture strand which has been passed through the eyelet 18. The eyelet 18 is located on the shaft portion 16 of the bone anchor 22 such that the transverse axis of the eyelet 18 intersects the longitudinal axis of the bone anchor 22.

The generally cone-shaped head 14 of the bone anchor 22 is located at an end of the shaft portion 16 opposite the end having the eyelet 18. The apex of the generally cone-shaped head 14 is a point 24 which is suitable for piercing and being driven into bone. The diameter of the generally cone-shaped head 14 increases along a longitudinal direction from the point 24 towards the eyelet 18.

As discussed above with reference to Figures 1-4, the bone anchor 22 has at least two, preferably three or more cutting edges 26. The cutting edges 26 are preferably sharp. In the disclosed embodiment in Figure 5, the cutting edges 26 are defined by curved or scalloped surfaces.

The collar member 20 is rotatably fitted over the shaft portion 16 to form the assembled bone anchor 22 as shown in Figure 5. While there is no need to permanently secure the collar member 20 to the generally cone-shaped head 14, the collar member 20 may nevertheless be securely attached to the generally cone-shaped head 14. It will be appreciated, however, that by permitting the generally cone-shaped head 14 to rotate freely with respect to collar member 20, a suture strand can be rotated by the surgeon after implantation to a position where the

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forces acting on the suture strand by the bone anchor 22 are more evenly distributed around the region of the shaft portion 16 adjacent to the eyelet 18.

In addition, it should also be appreciated that the two-piece construction of the bone anchor affords machining advantages over a single-piece bone anchor. That is, it is easier to machine each of these two components (i.e., the collar member 20 and the bone anchor 22, where the bone anchor 22 includes the head 14 and the shaft portion 16) separately and subsequently to assemble them together, as opposed to machining the same basic structural features from a single piece of material

Another aspect of the invention is a bone anchor implantation device comprising a hooked-shaped shaft with a bone anchor mount adapted to releasably engage at the distal end of the shaft a bone anchor with at least two cutting edges. The bone anchor mount generally points toward the handle, such that the user can drive the bone anchor into the bone by simply pulling back on the handle and using the patient's body weight to provide an opposing force. Preferably, the longitudinal axis of the bone anchor mount is aligned with the longitudinal axis of the handle.

A representative bone anchor implantation device having a hooked elongated member and a bone anchor with cutting edges are shown in Figure 6. The bone anchor implantation device 210 has a handle 212 having a proximal end 214 and a distal end 216. The handle 212 may be made of a variety of materials, such as plastic or metal. The elongated member 220 may be made of a variety of materials such as stainless steel, engineering plastics, fiber-bearing components, or other materials. Preferably, the elongated member 220 is made of stainless steel.

In the embodiment of the bone anchor implantation device 210 shown in Figure 6, the elongated member 220 comprises a straight proximal section 222, a first generally curved section 224 distal to the straight proximal section, a second generally curved section 226 distal to the first curved section, a third generally curved section 228 distal to the second curved section, and a fourth generally

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curved section 230 distal to the third curved section. However, one of skilled in the art would appreciate that the elongated member 220 could also comprise a series of straight segments angled relative to one another to form a hook.

The straight proximal section 222 of the elongated member 220 has an annular shoulder 232 which abuts the distal end 216 of the handle. The straight proximal section 222 passes through a lumen (not shown) extending through the handle. The proximal end of the straight proximal section 222 has a threaded bore which is adapted to receive a screw 236 which secures the elongated member 220 to the handle.

The handle 212 defines an axis at the proximal end of the anchor implantation device 210, and then moving distally from the handle 212 the elongated member 220 first curves away from the axis of the handle and then back toward the axis of the handle 212. The distal end of the elongated member 220 preferably is located in the vicinity of the axis of the handle 212. In some preferred embodiments, the elongated member 220 at the distal end can be generally perpendicular to the axis of the handle or can actually be curving back toward the handle 212.

A bone anchor mount 238 for releasably engaging a bone anchor 248 is attached to the distal end 240 of the fourth curved section 230 of the elongated member 220. Preferably, the bone anchor mount 238 is oriented at an angle of approximately 90° relative to the distal end 240 of the fourth curved section 230, as illustrated in Figure 6.

A variety of bone anchors can be releasably engaged to the bone anchor implantation device. In accordance with the invention, the bone anchor used with the device 210 is a bone anchor 248 having a generally cone-shaped head and cutting edges as described above with respect to Figures 1-5.

The bone anchor mount 238 is oriented so that the bone anchor 248 is pointed in the general direction of the handle 212. In one embodiment, the axis of

the bone anchor 248 is generally aligned with the axis of the handle 212, with the bone anchor pointed toward the handle 212.

The bone anchor mount 238 may be fabricated from the same materials as the elongated member 220 and may be attached to the elongated member 220 by a variety of methods such as brazing.

Although this invention has been described in terms of certain preferred embodiments, other embodiments which will be apparent to those of ordinary skill in the art in view of the disclosure herein are also within the scope of this invention. Accordingly, the scope of the invention is intended to be defined only by reference to the appended claims.

What is claimed is:

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CLAIMS

- 1 1. A bone anchor for use with a bone anchor implantation device
- 2 comprising a generally cone-shaped head having a wide end, a narrow end,
- 3 and at least two cutting edges wherein said cutting edges come together to
- 4 form a pointed tip at the narrow end.
- 1 2. The device of claim 1 wherein the cutting edges of the head are
- 2 defined by at least one flat surface.
- 1 3. The device of claim 1 wherein the cutting edges of the head are
- 2 defined by at least one curved surface.
- 1 4. The device of claim 1 wherein the head has three of the cutting
- 2 edges.
- 1 5. The device of claim 1 wherein the cutting edges comprise sharp
- 2 edges.
- 1 6. The device of claim 1 wherein said bone anchor comprises titanium.
- 1 7. The device of claim 1 further comprising a collar member disposed
- 2 near the wide end of the head.
- 1 8. The device of claim 1 further comprising a shaft with an eyelet for
- 2 receiving a suture, the shaft being coupled to the wide end of the head.
- 1 9. A device for inserting a bone anchor into a bone, comprising:
- a handle having a proximal end and a distal end,
- a hook-shaped shaft having a first and second end, said first end
- 4 being connected to the distal end of said handle,
- a bone anchor mount connected to the second end of said shaft, and

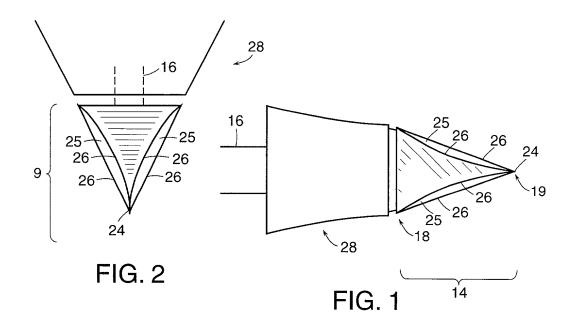
- a bone anchor releasably engaged to the bone anchor mount, the
- 7 bone anchor comprising a generally cone-shaped head with a wide end, a
- 8 narrow end, and at least two cutting edges wherein the cutting edges come
- 9 together to form a pointed tip at the narrow end.

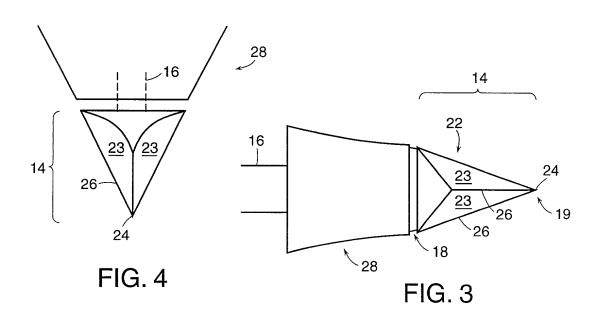
Bone Anchors For Bone Anchor Implantation Device

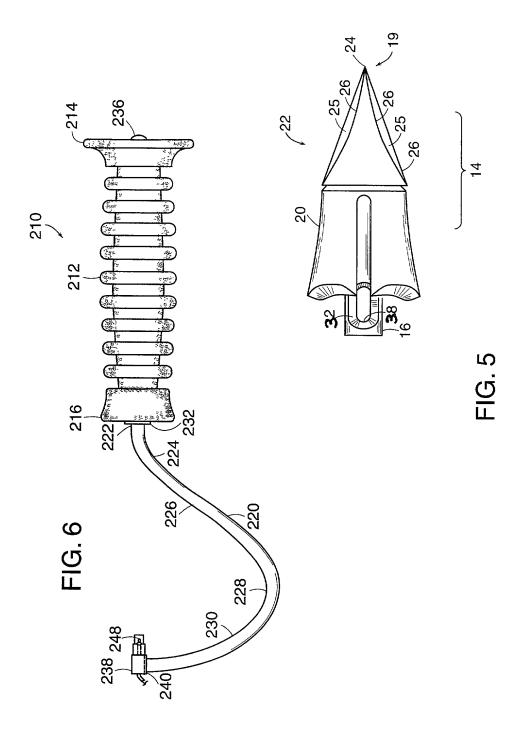
Abstract of the Disclosure

Bone anchors and bone anchor implantation devices can be used to maintain or improve urinary continence by suspending or stabilizing the bladder neck of a patient. The bone anchors have a generally cone-shaped head with two or more cutting edges which reduce the amount of force required to implant the bone anchor into bone.

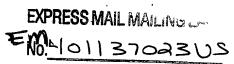
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DECLARATION AND POWER		Attorn	ey Docket No.	BSC	2-035			
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OF ATTORNEY FOR UTILITY		rustr	vanied inventor	Gen	man et al.			
OR DESIGN			COMPLETE IF KNOWN					
PATENT APPLICATION		Applic	cation Serial Number					
☐ Declaration ☐ Dec	laration	Filing	Date	January 26, 1999				
Submitted with Subm	nitted after Initial	Group	Art Unit	Not	Not yet assigned.			
Initial Filing Filing	g (surcharge	Exami	ner Name	Not				
37 CI	FR 1.16(e) required)							
		1						
As a below named inventor, I	hereby declare that:							
My residence, post office addre	ss, and citizenship are	as stated	below next to my nam	ie.				
I believe I am the original, first names are listed below) of the s	and sole inventor (if or	nly one r	name is listed below) or	r an or	iginal, first and	joint inventor (if plural		
						ntion entitled:		
В	BONE ANCHORS FOR BONE ANCHOR IMPLANTATION DEVICE							
the specification of which		(Title	of the Invention)					
is attached hereto								
OR								
	January 26, 199	19	as United States Appli	ication	Serial Number	or PCT International		
Application Number 09/238,663 and was amended on (MM/DD/YYYY) (if applicable).								
I hereby state that I have review		contents	of the above identified	d speci	fication, includ	ing the claims, as amended		
by any amendment specifically referred to above.								
I acknowledge the duty to discle								
I hereby claim foreign priority be certificate, or 365(a) of any PCI	enems under 35 U.S.C international applicat	ion which	-(d) or 365(b) of any fo th designated at least or	oreign ne cou	application(s) i	for patent or inventor's		
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Additional foreign application numbers are listed on a supplemental priority data sheet attached hereto.								
I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below. Application Serial Number(s) Filing Date (MM/DD/YYYY)								
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Declaration and Power of Attorney for Utility or Design Patent Application Serial No.: 09/238,663

Page 2 of 3

DECLARATION - Utility or Design Patent Application							
I hereby claim the benefit under 35 U United States of America, listed belo States or PCT International application which is material to patentability as of PCT international filing date of this a	ow and, insofar as the subje ion in the manner provided defined in 37 CFR 1.56 wh	ect matter of of by the first r	each of the claims of the paragraph of 35 U.S.C.	his application is 112. I acknowle	not disclosed in the prior United		
U.S. Parent Application of Serial Number	or PCT Parent		Parent Filing Date (MM/DD/YYYY)		Parent Patent Number (if applicable)		
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As a named inventor, I hereby appoir and Trademark Office connected then	nt the following registered rewith: Customer Nu	practitioners imber		ication and to tra	Place Customer Number Bar Code Label Here		
	Registration		Ť – –		Registration		
Name	Number	` !	Name		Number		
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Isabelle A.S. Blundell	43,321	!	Marianne McLaugh		42,870		
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Jerrie L. Chiu	41,670	ļ	Edmund R. Pitcher	. 1	27,829		
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Declaration and Power of Attorney for Utility or Design Patent Application

Serial No.: 09/238,663

Page 3 of 3

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Name of Sole or First	t Inventor: A petition has been filed for this unsigned inventor					or			
Given Name (first and middle [if any])				Family Name or Surname					
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Inventor's Signature	Signature Harman Solman				Date 3/5/59				
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☐ Additional inventor	s are being named	on the supp	olemental	Additional	Inventor(s) sheet(s) att	ached heret	0,	
Name of Additional Joint Inventor, if any: A petition has been filed for this unsigned inventor									
Given N	ame (first and mi	ddle [if any])		Family Name or Surname					
David J. Sauvageau									
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Name of Additional Joint Inventor, if any: A petition has been filed for this unsigned inventor									
Given Name (first and middle [if any])				Family Name or Surname					
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Inventor's Signature						Date			
Street Address				Citizensh	ip				
	City		State		Zip		Country		
Post Office Address									
	City		State		Zip		Country		